



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - Public distribution

Date: 10/23/2008

GAIN Report Number: JA8066

Japan

Food and Agricultural Import Regulations and Standards

Designation of food additives - 2,3-Dimethylpyrazine, et al.

2008

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Tokyo

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Report Highlights:

On October 16, 2008, the Japanese Government announced the planned approval of the food additives, 2,3-Dimethylpyrazine, 2,5-Dimethylpyrazine and 2,6-Dimethylpyrazine. The comment period will close on October 30, 2008

Includes PSD Changes: No
Includes Trade Matrix: No
Trade Report
Tokyo [JA1]
[JA]

Summary

On October 16, 2008. The Japanese Ministry of Health Labour and Welfare (MHLW) announced the planned approval of the food additives, 2,3-Dimethylpyrazine, 2,5-Dimethylpyrazine and 2,6-Dimethylpyrazine. The period for sending comments on these changes ends October 30, 2008. If you have comments it is best to send directly to MHLW as soon as possible. However, MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

The comments can be either Japanese or English.

If you have comments, please send them directly to the Japanese Government at:

Standards and Evaluation Division,
Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
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Designation of Food Additives

Purpose and background

The Ministry of Health, Labour and Welfare is going to newly designate three substances as authorized food additives and withdraw the designation of one substance as an authorized food additive.

Under Article 10 of the Food Sanitation Law, food additives can be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. When use standards or compositional specifications are established for food additives based on Article 11 of the law, those additives are not permitted to be used or marketed unless they meet these standards or specifications. The withdrawal of designation is also based on Article 10. Once the designation of a food additive is withdrawn, use standards and compositional specifications for the substance are withdrawn at the same time.

In response to a request from the Minister, the Subcommittee on Food Additives under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the authorization of the three substances (2,3-Dimethylpyrazine, 2,5-Dimethylpyrazine, 2,6-Dimethylpyrazine), and also discussed the adequacy of the withdrawal of the designation of Sodium Starch Phosphate as an authorized food additive. The subcommittee has concluded as follows.

Outline of conclusion

The Minister should designate 2,3-Dimethylpyrazine, 2,5-Dimethylpyrazine, 2,6-Dimethylpyrazine, based on Article 10 of the Food Sanitation Law, as food additives unlikely to harm human health and establish compositional specifications for these substances, based on Article 11 of the law (see Attachments 3-1, 3-2, and 3-3).

Also, the Minister should withdraw the designation of Sodium Starch Phosphate based on Article 10 of the Food Sanitation Law and withdraw its compositional specifications and use standards based on Article 11 of the law (see Attachments 3-4).

Additional Information

Progress in the designation procedure of food additives that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan (Attachment 3-5)

Attachment 8-1

2,3-Dimethylpyrazine

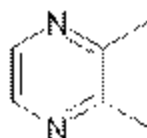
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 2,3-Dimethylpyrazine

Structural formula



Molecular formula $C_6H_6N_2$

Mol. Weight 108.14

Chemical name, CAS number 2,3-Dimethylpyrazine [3910-89-4]

Content 2,3-Dimethylpyrazine mainly consists of 2,3-dimethylpyrazine itself and contains not less than 95.0% of $C_6H_6N_2$ as a mixture of 2,3-dimethylpyrazine, 2,5-dimethylpyrazine, and 2,6-dimethylpyrazine.

Description 2,3-Dimethylpyrazine occurs as a colorless to light yellow liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of 2,3-dimethylpyrazine, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

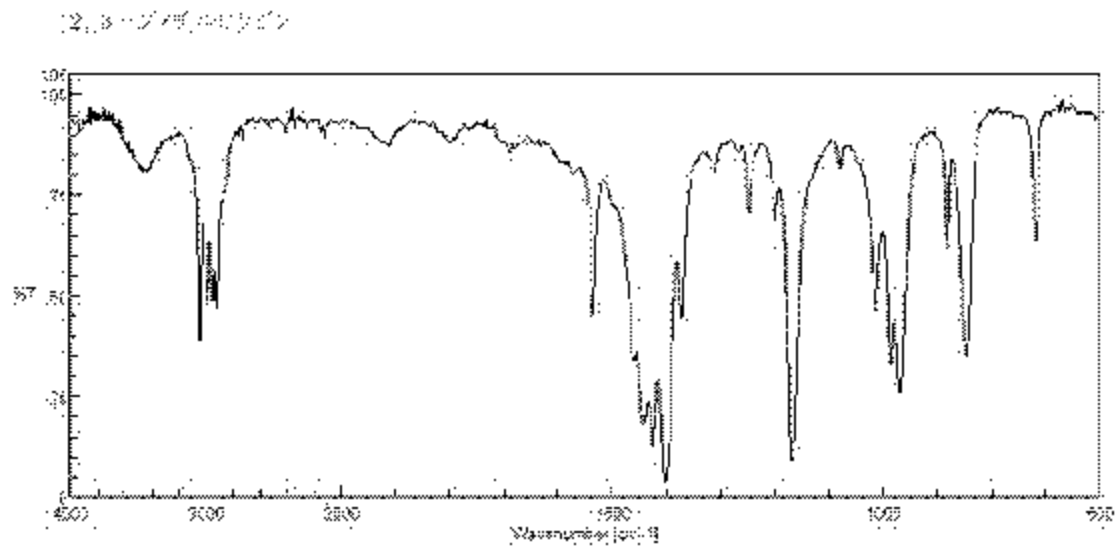
Purity

(1) Refractive index n_D^{20} : 1.501–1.510.

(2) Specific gravity d_4^{20} : 0.997–1.000

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (1).

Reference Spectrum



Attachment 8-2

2,5 Dimethylpyrazine

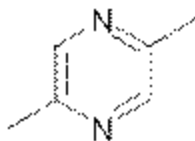
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 2,5-Dimethylpyrazine

Structural formula



Molecular formula $C_6H_6N_2$

Mol. Weight 106.14

Chemical name, CAS number 2,5-Dimethylpyrazine [128-82-0]

Content 2,5-Dimethylpyrazine mainly consists of 2,5-dimethylpyrazine itself and contains not less than 98.6% of $C_6H_6N_2$ as a mixture of 2,5-dimethylpyrazine, 2,3-dimethylpyrazine, and 2,6-dimethylpyrazine.

Description 2,5-Dimethylpyrazine occurs as a colorless to light yellow liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of 2,5-dimethylpyrazine, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

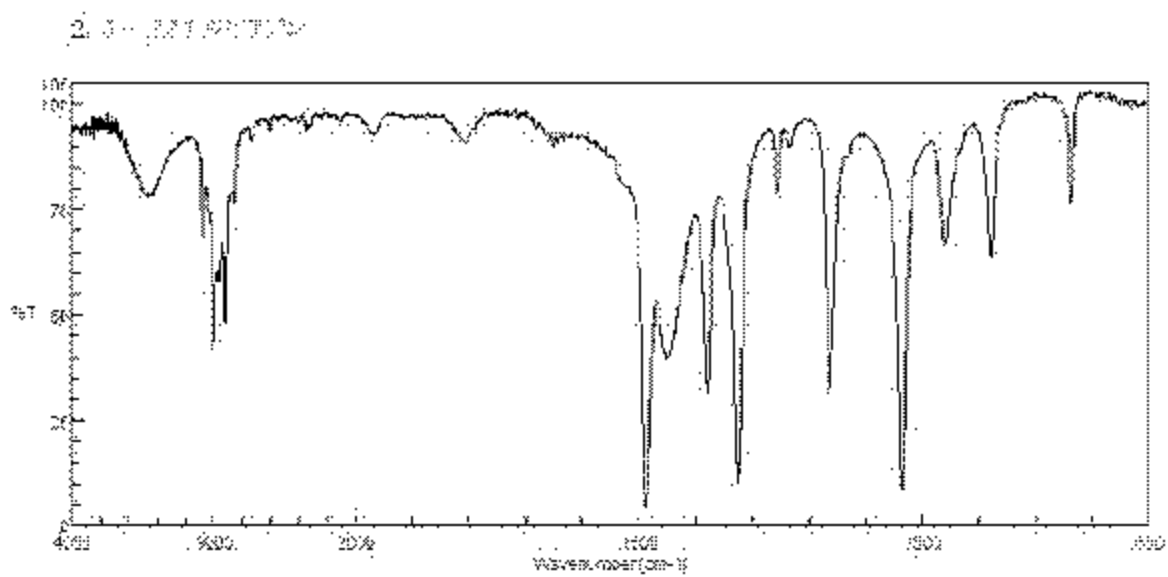
Purity

(1) Refractive index n_D^{20} : 1.497-1.503.

(2) Specific gravity d_4^{20} : 0.982-1.000

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (1).

Reference Spectrum



Attachment 3-8

2,6-Dimethylpyrazine

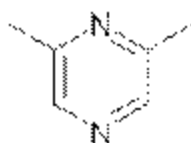
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 2,6-Dimethylpyrazine

Structural formula



Molecular formula $C_6H_6N_2$

Mol. Weight 106.14

Chemical name, CAS number 2,6-Dimethylpyrazine [108-50-9]

Content 2,6-Dimethylpyrazine mainly consists of 2,6-dimethylpyrazine itself and contains not less than 98.0% of $C_6H_6N_2$ as a mixture of 2,6-dimethylpyrazine, 2,3-dimethylpyrazine, and 2,5-dimethylpyrazine.

Description 2,6-Dimethylpyrazine occurs as white to yellow crystals having a characteristic odor.

Identification Melt 2,6-Dimethylpyrazine by warming, hold it between two prewarmed optical plates, immediately determine the infrared absorption spectrum with care to avoid solidification, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wave numbers.

Purity

(1) Melting point 35–40 °C

Assay Dissolve about 0.2 g of 2,6-dimethylpyrazine, weighed accurately, in ethanol to make exactly 20 ml, and proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (1).

Reference Spectrum

